

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PFIZER INC.,)	
PFIZER IRELAND PHARMACEUTICALS,)	
WARNER-LAMBERT COMPANY, and)	
WARNER-LAMBERT COMPANY LLC,)	
)	
Plaintiffs,)	
)	
v.)	Civil Action No. 08-948 (LDD)
)	
APOTEX INC. and)	
APOTEX CORP.,)	
)	
Defendants.)	
_____)	

**PLAINTIFFS' BRIEF IN OPPOSITION TO DEFENDANTS APOTEX INC.'S AND
APOTEX CORP.'S FED. R. CIV. P. 12(b)(1) AND (6) MOTION TO DISMISS
ALL CLAIMS OF INFRINGEMENT BASED ON THE '995 PATENT**

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I. Introduction

Pfizer Inc., Pfizer Ireland Pharmaceuticals, and Warner-Lambert Company LLC (formerly Warner-Lambert Company) (collectively “Pfizer” or “Plaintiffs”) hereby oppose defendants Apotex Inc.’s and Apotex Corp.’s (collectively “Apotex” or “Defendants”) motion to dismiss Pfizer’s claims of infringement of U.S. Patent No. 5,273,995 (“the ‘995 patent”) under Fed. R. Civ. P. 12(b)(1) and (6) (D.I. 34 [motion]; D.I. 35 [brief ISO motion—Apotex’s “Surrender Motion”]). Because Pfizer’s right to enforce the ‘995 patent as pleaded in the Complaint and Amended Complaint is neither affected nor abated by the grant of U.S. Reissue Patent No. 40,667 (“the RE667 patent”), Apotex’s Surrender Motion must be denied.

The reissue statute provides that surrender “shall take effect upon the issue of the reissued patent,” 35 U.S.C. § 252, and that “the Director may issue several reissued patents,” 35 U.S.C. § 251. In September 2000, the Patent Office adopted a rule that allowed more than one reissue application on the same patent to be granted at different times, a procedure Pfizer followed here. The question, therefore, is not whether surrender will occur, but when does it occur where, as here, there are multiple reissue applications, including one with substantially identical claims as in the original that is still pending before the Patent Office?¹ When read as a whole, the reissue statute, including its non-abatement and continuity provisions, unambiguously requires that surrender occur when all reissue prosecution is finished. As we explain below, the intent of Congress in enacting these provisions was for original patents to remain enforceable until the reissue process is complete. The Patent Office, following the Federal Circuit’s *Graff* decision, has held that in this circumstance surrender necessarily must occur at the end of the prosecution of the last pending reissue application. According to the Patent Office, if, as Apotex argues here,

¹ In this context, surrender means to give up the right to the original patent in favor of the reissue patent. It does not require physical surrender (i.e., delivery) of the actual Letters Patent to the Patent Office.

a complete surrender occurs on grant of the first reissue, then there would be nothing left to surrender on grant of the subsequent reissue(s). Apotex's Surrender Motion, which depends on abatement and ignores continuity, directly conflicts with both (1) the provisions of the reissue statute and (2) the Patent Office's views, rules, and practice.

II. Nature and Stage of the Proceeding

Pfizer filed the Complaint in this action on December 17, 2008 in response to Apotex's submission to the Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 90-548 seeking to market a generic version of atorvastatin calcium tablets.² (D.I. 1.) As set forth in the Complaint, Apotex's ANDA filing is an infringement of Pfizer's '995 patent under 35 U.S.C. § 271(e)(2). (D.I. 1, ¶ 33; D.I. 25, ¶ 50.) On March 17, 2009, the Patent Office granted the RE667 patent to Pfizer, from the first of two reissue applications based on the '995 patent. The RE667 patent claims subject matter from the '995 patent directed specifically to the calcium salt of atorvastatin. The other claims of the '995 patent, which are not of the same scope and/or precise subject matter as the '667 reissue claims, but that Apotex infringes nonetheless, are still being prosecuted in the Patent Office in the second reissue application. *See* Section IV.B., *infra*. Pfizer promptly amended its Complaint in this action on March 23, 2009 to add a count for infringement of the RE667 patent. (D.I. 25, ¶¶ 51-56.)

Following the filing of Pfizer's Amended Complaint, Apotex withdrew as moot a previously-filed motion to dismiss based on alleged surrender of the '995 patent. (D.I. 22.) Apotex subsequently re-filed its Surrender Motion on May 4, 2009. (D.I. 34-35.) The Surrender

² Atorvastatin is a potent cholesterol lowering drug. Pfizer sells atorvastatin, in the form of its calcium salt, under the brand name Lipitor[®]. Lipitor[®] is and has been for many years, the world's best selling drug, with annual sales, world-wide, exceeding \$12 billion dollars.

Motion seeks dismissal only of the infringement claims based on the '995 patent. Therefore, this case will proceed based at least on the RE667 patent regardless of the outcome of the Surrender Motion.³ This is Pfizer's opposition to Apotex's Surrender Motion.

III. Summary of Argument

1. The grant of the RE667 patent has neither affected nor abated Pfizer's right to sue Apotex for infringement of the '995 patent because the reissue statute, 35 U.S.C. §§ 251-252, properly construed, mandates that surrender of rights does not occur until the conclusion of all reissue prosecution in the Patent Office. The application that led to the RE667 patent is not the only reissue application based on the '995 patent. A second reissue application—a continuation of the application that resulted in the RE667 patent—maintains Pfizer's '995 patent rights. Indeed, the reissue statute expressly states that the "Director may issue several reissued patents for...the thing patented." 35 U.S.C. § 251.

2. Apotex's position that the '995 patent was entirely surrendered immediately upon grant of the RE667 patent is contrary to the express language of 35 U.S.C. §§ 251-252. The statute clearly states that a "reissued patent, to the extent that its claims are substantially identical with the original patent, shall constitute a continuation thereof and have effect continuously from the date of the original patent," and that "surrender shall not affect any action then pending nor abate any cause of action then existing." 35 U.S.C. § 252. Nonetheless, Apotex demands that this Court terminate Pfizer's rights in the '995 patent despite the unambiguous language continuing Pfizer's patent rights through the reissue process as long as claims remain that are substantially identical to those in the original patent. The statute does not permit the termination

³ The filing of the Complaint triggered a stay preventing FDA from approving Apotex's ANDA for thirty months. As set forth in 35 U.S.C. § 252, the outcome of the present Surrender Motion will not affect the stay because the RE667 patent will remain in the case in any event.

of Pfizer's patent rights while the '995 reissue prosecution continues. Apotex's position is contrary to the plain meaning of the reissue statute as properly construed.

3. Apotex's position is also contrary to the intent of Congress in enacting the reissue statute. The present reissue statute was created, *inter alia*, to do two things: (1) allow patentees to enforce their original patents while reissue applications are pending; and (2) ensure continuity of actions brought under the original patent once a reissue patent is granted. In particular, the reissue statute was specifically designed to allow a patentee to enforce its patent during the reissue process. To hold, as Apotex urges, that Pfizer has surrendered all of its '995 patent rights while it is currently prosecuting substantially identical claims in the reissue of the same patent in the Patent Office would frustrate Congress's intent to prevent exactly this loss of patent rights.

4. The Patent Office—in addressing this same issue—has determined that the surrender of a patent does not occur until all of the continuation or divisional reissue applications on that patent are resolved. Other than the unsupported assertion that the Patent Office's determination is "pure dicta" (Surrender Motion at 28), Apotex points to no authority and makes no argument why the Patent Office's interpretation (and implementation) of the reissue statute is improper. Consistent with the express language of the statute, the intent of Congress, and the Federal Circuit's decision in *In re Graff*, 111 F.3d 874, 877 (Fed. Cir. 1997), the Patent Office, while interpreting the statute and its own regulations, has determined that "the surrender of a defective patent does not occur until all of the continuation or divisional reissue applications are issued." *Ex Parte Okamoto*, 2006 WL 2523548, at *4 (B.P.A.I. Oct. 21, 2002) (Declaration of Daniel C. Mulveny ("Mulveny Decl.") ¶ 2, Ex. A). The rules of the Patent Office relating to the timing of multiple reissue patent grants and associated surrender of the original patent are within the scope of the Patent Office's congressionally delegated authority. To the extent that

the Court finds any ambiguity in the reissue statute, the Patent Office's determinations are entitled to *Chevron* deference. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43 (1984). Under the Patent Office rules, the '995 patent remains in force because there is a pending reissue application with claims at least substantially identical to some claims in the '995 patent. Therefore, this Court has subject matter jurisdiction.

5. In sum, the plain meaning of the reissue statute, combined with clear expressions of Congress's intent in the legislative record and the Patent Office's implementation of the reissue statute, compel the same conclusion: Pfizer's right to enforce the '995 patent claims at issue in this case remains unaltered during the continued reissue proceedings in the Patent Office. Accordingly, this Court continues to have subject matter jurisdiction over Pfizer's infringement claims based on the '995 patent and Apotex's motion must be denied.

IV. Statement of Facts

A. Patent Office Procedure to Correct Defects

When an issued patent is found to contain one or more defects, the patentee may request that the Patent Office reissue the patent to correct the defects. 35 U.S.C. § 251. This is done by filing a reissue application. 37 C.F.R. § 1.171. A reissue application is subject to substantially the same requirements as an original application (*see* Surrender Motion at 10-11), and in many respects is treated in the same way. 37 C.F.R. § 1.171, 1.176(a); *Graff*, 111 F.3d at 877. However, the filing of a reissue application is a low risk procedure. If the Patent Office ultimately rejects the reissue application, the applicant can abandon the application, the original patent is returned to the applicant (if it was given to the Patent Office), and the original patent remains in force for the duration of its normal term. *See Dresser Indus., Inc. v. Ford Motor Co.*, 530 F. Supp. 303, 309-10 (N.D. Tex. 1981) (explaining that the reissue procedure provides "a mechanism whereby, with little risk," an inventor can correct a defect), *superseded by regulation*

on other grounds, see 37 C.F.R. § 1.56, 1095 *Official Gazette Pat. Office* 16 (Oct. 11, 1988) (Mulveny Decl. ¶ 3, Ex. B) (modifying regulation to prohibit *sua sponte* ordering of reissue upon a request for reexamination). “If reissue is refused...the patentee retains all property rights in his existing patent.” *Id.* at 310. This is so because, “the original patent is surrendered only if, and when, the application for reissue has been accepted and the PTO...causes the original patent to be reissued in amended form.” *Id.*

Just like an original patent application, a patentee may file multiple reissue applications based on the same patent. For example, the patentee may file a first reissue application and then one or more continuation reissue applications. 37 C.F.R. § 1.177(a); see also *Graff*, 111 F.3d at 877 (“Section 251[2] has the effect of assuring that a different burden is not placed on divisional or continuation reissue applications, compared with divisions and continuations of original applications”); MPEP 8th Ed., Rev. 7, § 1451 (2008) (Mulveny Decl. ¶ 4, Ex. C) (“Prosecution of a continuation of a reissue application . . . will be permitted (despite the existence of the pending parent reissue application) . . .”).

B. Background of the ‘995 Patent

Lipitor[®] is the brand name for Pfizer’s atorvastatin calcium medication, which is presently indicated for the prevention of cardiovascular disease and high cholesterol levels in the bloodstream. The FDA approved Pfizer’s NDA for Lipitor[®] in 1996. Lipitor[®] is, and has been for many years, the most popular pharmaceutical in the world, having annual sales, world-wide, of over twelve billion dollars. Pursuant to 21 U.S.C. § 355(b)(1), Pfizer listed the ‘995 patent and the RE667 patent, among others, in the Orange Book for Lipitor[®]. (D.I. 25 ¶¶ 13-14.) Taking into account grants of pediatric exclusivity (21 U.S.C. § 355a), which effectively extend the patent expiration date, the ‘995 patent and the RE667 patent both expire June 28, 2011.

In a prior litigation between Pfizer and Ranbaxy involving claim 6 of the ‘995 patent, this Court found the claim to be valid and infringed. *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 405 F. Supp. 2d 495, 525-26 (D. Del. 2005). However, the Court of Appeals for the Federal Circuit (“Federal Circuit”) reversed based solely on a technical defect in the wording of claim 6 of the ‘995 patent—the Federal Circuit held that claim 6 was invalid because it recited subject matter outside the scope of the claim from which it depended. *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1291-92 (Fed. Cir. 2006). The Federal Circuit recognized that claim 6 was directed to “what might otherwise have been patentable subject matter,” and “could have been properly drafted either as dependent from [another claim] or as an independent claim.” *Id.* at 1292.

The technical defect in claim 6 of the ‘995 patent is also contained in other ‘995 claims, but all are correctable by reissue.⁴ 35 U.S.C. § 251. Thus, Pfizer filed two reissue applications based on the ‘995 patent. The first reissue application was filed January 16, 2007 as U.S. Pat. App. No. 11/653,830 (“the ‘830 reissue application”). (Mulveny Decl. ¶ 5, Ex. D.) The ‘830 reissue application included corrected claim 6 of the ‘995 patent and two new claims. (Mulveny Decl. ¶ 6, Ex. E.) The second reissue application was filed on October 10, 2007—while the ‘830 reissue application was still pending—as U.S. Pat. App. No. 11/973,897 (“the ‘897 continuation reissue application”). (Mulveny Decl. ¶ 7, Ex. F.) This second reissue application sought to correct the same drafting defect in other ‘995 claims and it satisfied all requirements to constitute a continuation reissue application of the ‘830 reissue application. The ‘897 continuation reissue application includes all of the claims of the ‘995 patent (corrected as needed), except claim 6,

⁴ Without explanation, Apotex alleges several times that the defects in the ‘995 patent are not the type that are correctable by reissue. Apotex is mistaken. The Patent Office already held that the claim-drafting defect was correctable by reissue. However, the issue is irrelevant to the present Surrender Motion.

and one additional new claim.⁵ (Mulveny Decl. ¶ 8, Ex. G.) The ‘830 reissue application issued on March 17, 2009 as the RE667 patent with the technical defect in claim 6 corrected and the two new claims. (Mulveny Decl. ¶ 9, Ex. H.) The ‘897 continuation reissue application is still pending and in active prosecution before the Patent Office. (Mulveny Decl. ¶ 10, Ex. I.) Significantly, the claims pending in the ‘897 continuation reissue application that were carried forward from the ‘995 patent remain identical in scope to their corresponding claims in the ‘995 patent. (Mulveny Decl. ¶¶ 8, 11, Exs. G, J.)

V. Argument

A. Motion to Dismiss

In evaluating a motion to dismiss under Fed. R. Civ. P. 12(b)(6), the Court must accept as true all material allegations of the complaint. *Spruill v. Gillis*, 372 F.3d 218, 223 (3d Cir. 2004). “The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims.” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997) (quotation omitted). The Court may grant a motion to dismiss only if, after “accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief.” *Maio v. Aetna, Inc.*, 221 F.3d 472, 481-82 (3d Cir. 2000) (quotation omitted).

The standards relevant to Rule 12(b)(6) also apply to a facial challenge under Fed. R. Civ. P. 12(b)(1). *Samsung Elecs. Co. v. ON Semiconductor Corp.*, 541 F. Supp. 2d 645, 648 (D. Del. 2008). Thus, the Court must accept all factual allegations in the Complaint as true, and the

⁵ The ‘830 reissue application was ultimately limited to corrected claim 6 (and the two new claims) in order to expedite its reissue. Claims 1-5 and 7-12 of the ‘995 patent remain valid and in force in the ‘995 patent while the ‘897 continuation reissue application is pending. It is a long-standing rule that “each claim of a patent is treated as if it was a separate patent.” *Dollar Elec. Co. v. Syndevco, Inc.*, 205 U.S.P.Q. 949, 959, 1979 WL 25101 (E.D. Mich. Sept. 10, 1979), *aff’d*, 688 F.2d 429 (6th Cir. 1982).

Court may only consider the complaint and documents referenced in or attached to the complaint. *Gould Elecs., Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000). On the other hand, when reviewing a factual challenge to subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1), the Court is not confined to the allegations of the complaint. *Mortensen v. First Fed. Sav. & Loan*, 549 F.2d 884, 891 (3d Cir. 1997). The Court may consider evidence outside the pleadings, including “affidavits, depositions, and testimony to resolve any factual issues bearing on jurisdiction.” *Gotha v. United States*, 115 F.3d 176, 179 (3d Cir. 1997).

“Dismissal for lack of subject-matter jurisdiction because of the inadequacy of the federal claim is proper only when the claim is so insubstantial, implausible, foreclosed by prior decisions of [the Supreme Court], or otherwise completely devoid of merit as not to involve a federal controversy.” *Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 89 (1998) (internal quotation marks omitted).

B. The ‘995 Patent Has Not Been Surrendered

There is no dispute that surrender of the ‘995 patent will occur when the patent is totally reissued. The question before this Court is one of timing—whether surrender occurs when the patent is fully reissued as the statute requires, or when the patent is only partially reissued as Apotex suggests. The reissue statute states that a patent “shall” be surrendered “upon the issue of the reissued patent.” 35 U.S.C. § 252 ¶ 1. The reissue statute also expressly authorizes the grant of multiple reissue patents. 35 U.S.C. § 251 ¶ 2. Therefore, when more than one application to reissue the same patent is involved, the statute necessarily mandates that the original patent is not surrendered until the last reissue patent is issued. This is the most logical construction of the statute. And this is the construction followed by the Patent Office, and the construction that comports with the non-abatement and continuation provisions of the statute.

For these reasons, the '995 patent has not been surrendered by issuance of the RE667 patent as explained below.

(1) The Express Language of the Statute Requires Surrender to Occur Upon the Grant of the Last Reissue Patent

When construing a statute, the first task is “to try to determine congressional intent, using traditional tools of statutory construction.” *Dole v. United Steelworkers of Am.*, 494 U.S. 26, 35 (1990) (quotations omitted). Statutory construction begins with the language of the statute itself. *Miller v. Dep’t of Army*, 987 F.2d 1552, 1555 (Fed. Cir. 1993).

(a) The Reissue Statute Must be Read as a Whole

“All statutes must be construed in light of their purpose.” *Haggar Co. v. Helvering*, 308 U.S. 389, 394 (1940). “To discern Congress’ intent we examine the explicit statutory language and the structure and purpose of the statute.” *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 138 (1990) (citations omitted). In evaluating the statutory language, “we are not guided by a single sentence or member of a sentence” *Dole*, 494 U.S. at 35; see *BlackLight Power, Inc. v. Rogan*, 295 F.3d 1269, 1273 (Fed. Cir. 2002) (citing *Dole*). Statutory provisions are to be “evaluated in light of the language of the Act as a whole.” *Offshore Logistics, Inc. v. Tallentire*, 477 U.S. 207, 220-21 (1986).

The full text of 35 U.S.C. § 252 ¶ 1 reads as follows:

The surrender of the original patent shall take effect upon the issue of the reissued patent, and every reissued patent shall have the same effect and operation in law, on the trial of actions for causes thereafter arising, as if the same had been originally granted in such amended form, but in so far as the claims of the original and reissued patents are substantially identical, such surrender shall not affect any action then pending nor abate any cause of action then existing, and the reissued patent, to the extent that its claims are substantially identical with the original patent, shall constitute a continuation thereof and have effect continuously from the date of the original patent.

35 U.S.C. § 252 ¶ 1 (emphasis added). In addition, the reissue statute states that “the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention” 35 U.S.C. § 251 ¶ 1. Further, the statute expressly states that “[t]he Director may issue several reissued patents for . . . the thing patented.” 35 U.S.C. § 251 ¶ 2. All of these statutory provisions must be read together in construing the statute. *Offshore Logistics*, 477 U.S. at 220-21. As such, construction of one statutory provision must not frustrate the purpose of another provision. *Superior Fireplace Co. v. Majestic Prods. Co.*, 270 F.3d 1358, 1371 (Fed. Cir. 2001). Indeed, “statutory interpretation is a ‘holistic endeavor’ that requires consideration of a statutory scheme in its entirety.” *Id.* at 1369 (quoting *Vectra Fitness, Inc. v. TNWK Corp.*, 162 F.3d 1379, 1383 (Fed. Cir. 1998)). Thus, the relevant provisions of the reissue statute must all be given effect:

- “[t]he Director may issue several reissued patents for...the thing patented” 35 U.S.C. § 251 ¶ 2.
- “surrender of the original patent shall take effect upon the issue of the reissued patent” 35 U.S.C. § 252 ¶ 1.
- “in so far as the claims of the original and reissued patents are substantially identical, such surrender shall not affect any action then pending nor abate any cause of action then existing” 35 U.S.C. § 252 ¶ 1.
- “the reissued patent, to the extent that its claims are substantially identical with the original patent, shall constitute a continuation thereof and have effect continuously from the date of the original patent” 35 U.S.C. § 252 ¶ 1.
- “the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention.” 35 U.S.C. § 251 ¶ 1.

In a situation where, such as here, multiple reissue applications have been filed to correct an original patent, and the original patent is the subject of a pending action, a consistent reading of § 251 and § 252 requires that a cause of action asserting original claims cannot be abated (as to substantially identical claims in a still-pending reissue application) by the grant of only one of

the multiple reissue applications. The statute mandates that “surrender shall not affect any action then pending nor abate any cause of action then existing.” 35 U.S.C. § 252 ¶ 1. The express language of the statute prohibits surrender from occurring upon grant of a first reissue in this circumstance.⁶ The key facts here are: (1) one reissue patent (the RE667 patent) has issued; (2) a further reissue application (the ‘897 reissue application) remains pending; (3) the claims of the original ‘995 patent are divided between them (claim 6 in the RE667 patent and the remaining claims in the ‘897 application); (4) following the RE667 patent grant, there are at least two sets of original claims (corrected as needed), those that have reissued (claim 6) in the RE667 patent and those that remain pending awaiting reissue (claims 1-5 and 7-12) in the ‘897 application; and (5) there are claims in each of the RE667 patent and the pending reissue application identical in scope to original claims in the ‘995 patent. When the reissue claims—both those that have been reissued and those that remain in reissue prosecution—are substantially identical to the original claims, as Apotex concedes here with respect to ‘667 claim 6 (Surrender Motion at 18-20), they are all entitled to protection from abatement. 35 U.S.C. § 252 ¶ 1. And any construction of the statute that would allow surrender of the original patent while pending substantially identical claims await reissue, would void the mandate that “surrender shall not affect any action then pending nor abate any cause of action then existing” as to the still-pending claims. For this

⁶ Apotex admits that its interpretation of the reissue statute would result in a lapse in coverage for the subject matter of the ‘995 patent, thereby affecting the current action (the dismissal Apotex seeks), and creating an abatement of Pfizer’s cause of action and a lack of continuity between the ‘995 patent and later reissued patent(s). (Surrender Motion at 30.) Apotex attempts to justify its demand that the Court ignore its proposed violations of the statutory non-abatement and continuity mandates by blaming Pfizer for the reissue process. *Id.* The procedures Pfizer followed to obtain the RE667 patent, while prosecuting the remaining ‘995 claims in the ‘897 continuation reissue application are expressly authorized by the rules of the Patent Office and approved by the Federal Circuit. 37 C.F.R. § 1.177; *In re Graff*, 111 F.3d at 876-77. With full knowledge of all the circumstances, the Patent Office has permitted these actions. Pfizer’s adherence to the appropriate statute and rules cannot be used as an excuse to ignore the mandatory provisions of the statute.

reason alone, Apotex's proposed construction of the statute is impermissible. *See Superior Fireplace*, 270 F.3d at 1371.

Further, the statute expressly mandates that a reissue patent "shall constitute a continuation thereof and have effect continuously from the date of the original patent." 35 U.S.C. § 252 ¶ 1. This requirement works hand in hand with the mandate that no pending causes of action be abated to ensure continuity of the inventor's rights. The statute establishes the requirement of continuity by ensuring that all subject matter covered by the original patent remains in force up to the exact moment when all of it is replaced by a reissue patent. *See Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 692 F. Supp. 1118, 1131 (N.D. Cal. 1988), *aff'd in relevant part, vacated in part*, 882 F.2d 1556 (Fed. Cir. 1989) (explaining that the statute "mandates surrender of the old only upon issuance of the new" when the original patent "has been completely replaced by the reissue.").

Apotex relies heavily on the provision of § 251, "the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention," in urging complete surrender of the '995 patent immediately upon grant of the RE667 patent. Apotex's interpretation not only ignores the non-abatement and continuation requirements of the statute, but also misconstrues the meaning of the phrase "the Director shall, on the surrender and the payment of the fee..., reissue the patent." Apotex misinterprets the phrase as a timing provision that requires complete surrender at the moment any reissue patent is granted, e.g., a strict requirement of simultaneous and complete surrender at the moment of the first reissue grant. (Surrender Motion at 15-16.) A closer examination of the provision reveals that surrender and payment of the fee is merely a condition of reissue, and not a concomitant requirement of the first reissue grant. Because the mandatory language "shall" refers to surrender and fee payment,

both must fully occur at the time of the first reissue grant under Apotex's interpretation. The fee referenced in the statute includes the issue fee for the reissue patent. 35 U.S.C. § 41(a)(4)(D). Each reissue patent requires payment of its own individual issue fee at the time the reissue patent is granted. *Id.*; *see also* 37 C.F.R. § 1.18(a) (setting forth the fee "for issuing each reissue patent") (emphasis added); 37 C.F.R. § 1.314 ("If applicant timely pays the issue fee, the Office will issue the patent") Therefore, when multiple reissue patents are granted at different times, multiple fees must be paid at different times. Accordingly, the phrase "the Director shall, on the surrender and the payment of the fee" cannot mean that surrender and fee payment must both be fully complete at the time the first reissue patent grants as Apotex suggests. Instead, the phrase establishes conditions of reissue, but does not inform as to the timing of surrender or payment. The Court should dismiss Apotex's tunnel view of the statute, and give effect to the statute as a whole, including the mandatory non-abatement and continuity provisions, which require that surrender not occur until all reissue patents have been issued or prosecution is concluded.

Apotex alleges that the non-abatement and continuity provisions of § 252 "simply address how far back temporally in coverage a claim in a reissue patent can go." (Surrender Motion at 17.) Apotex again misconstrues these provisions. As set forth above, the non-abatement and continuity provisions establish substantive rights to the patentee. These provisions guarantee that surrender will not affect any pending action nor abate any cause of action, and that all reissue patents have effect continuously from the date of the original patent. 35 U.S.C. § 252. These statutory mandates guarantee that legal actions can be maintained without interruption during the reissue process, and should be given effect by this Court. *Superior Fireplace*, 270 F.3d at 1371.

(b) The Federal Circuit Has Rejected Apotex's Interpretation

The statutory interpretation proposed by Apotex has been squarely rejected by the Federal Circuit. In *Ex Parte Graff*, 1996 WL 33693209 (B.P.A.I. Mar. 7, 1996) (Mulveny Decl. ¶ 12, Ex. K), a reissue application pending in the Patent Office contained allowed claims and rejected claims. *Id.* at *2. Similar to the facts of the present case, the patentee desired to expedite issuance of the allowed subject matter into a reissue patent so it cancelled the rejected claims, re-presented them in a continuation reissue application, and permitted the allowed claims to issue in a first reissue patent. *Id.* However, in *Ex Parte Graff*, the patent examiner then rejected the continuation reissue application, alleging that because the original patent had already been surrendered, there was nothing left to be reissued by the second application, and the Board of Patent Appeals and Interferences affirmed in error. *Id.* at *3,*6; *Graff*, 111 F.3d at 875. The Board held that: (1) the reissue statute only authorized multiple divisional reissue applications (not multiple continuation reissues); (2) the patentee had failed to properly demand multiple reissue patents in accordance with the statute; and (3) the original patent had been surrendered upon issue of the first reissue patent. *Ex Parte Graff*, 1996 WL 33693209 at *5-*6.

With respect to the third ground, the Board reasoned that the provision of 35 U.S.C. § 251 on which Apotex now relies—"the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent"—established a concomitant act of surrender as a strict requirement for the grant of a reissue patent. *Id.* at *6. The Board stated (in error) as to the continuation reissue application, that following the grant of a first reissue patent there no longer existed an original patent to be surrendered in support of the second reissue: "Nor could the [original] patent be surrendered upon issuance of the present second reissue application as required by the first paragraph of 35 U.S.C. § 251 since the [original] patent was already surrendered." *Id.*

In its opinion, the Federal Circuit explained the erroneous holding of the Board “that 35 U.S.C. § 251 does not authorize reissuance of the surrendered [original] patent through Mr. Graff’s second reissue application,” and squarely rejected it. *Graff*, 111 F.3d at 876. The Federal Circuit reversed the Board on all grounds relating to the allegedly “surrendered [original] patent,” stating that the Board’s rulings restricted a reissue application “beyond the strictures of the statute.” *Graff*, 111 F.3d at 876-877. The Federal Circuit’s decision in *Graff* indicated that where a continuing reissue application is still pending, the surrender of an original patent does not occur upon grant of the first of multiple reissue applications. Therefore, surrender of the original patent must occur when the last of multiple reissue applications is granted. A unanimous panel of three Administrative Patent Judges later confirmed this interpretation in *Ex Parte Okamoto*, 2006 WL 2523548, at *4 (“Implicit in *Graff* is that the surrender of a defective patent does not occur until all of the continuation or divisional reissue applications are issued consistent with Section 251, paragraphs 2 and 3.”)⁷

Should any doubt remain, 1 U.S.C. § 1 and Federal Circuit precedent on construction of the Patent Act show that the provision, “the surrender of the original patent shall take effect upon the issue of the reissued patent” (35 U.S.C. § 252, emphasis added), means upon the issue of all reissued patents, when more than one reissue application has been filed to correct the same patent. “In determining the meaning of any Act of Congress, unless the context indicates otherwise—words importing the singular include and apply to several persons, parties, or things.” 1 U.S.C. § 1. Thus, the phrase “upon the issue of the reissued patent” in 35 U.S.C. § 252 (emphasis added) should be read to include multiple reissue patents when several

⁷ The further significance of the *Okamoto* decision will be discussed in more detail in Section V.B.(3)(a), *infra*.

applications are pending. The Court of Customs and Patent Appeals (“CCPA”) has relied on this provision of 1 U.S.C. § 1 to interpret the Patent Act. *See In re Henriksen*, 399 F.2d 253, 258 (C.C.P.A. 1968) (holding that the singular form of the word “application” in 35 U.S.C. § 120 includes multiple applications).⁸ The court explained that, “Title 35 of the United States Code, like other recently codified titles, was written with 1 U.S.C. § 1 in mind” *Id.*; *see also Tafas v. Doll*, 559 F.3d 1345, 1362 (Fed. Cir. 2009) (quoting *Henriksen*, “[s]o read, ‘an application’ does not necessarily refer only to a single application.”).

Applying 1 U.S.C. § 1 and the Federal Circuit’s approach to construction of the Patent Act to § 252, the statute would read, “[t]he surrender of the original patent shall take effect upon the issue of the reissued patent[s],” meaning upon issue of all reissue patents stemming from a single original patent. This proper construction of § 252 directly supports and upholds the express statutory mandates that, “such surrender shall not affect any action then pending nor abate any cause of action then existing,” and that a reissue patent “shall constitute a continuation [of the original patent] and have effect continuously from the date of the original patent.” 35 U.S.C. § 252 ¶ 1.

(2) A Statutory Objective is to Maintain Inventors’ Rights While a Reissue Application is Pending

The intent of Congress and the purpose and objects of the reissue statute require surrender of an original patent only when all of its reissue applications have been issued or terminated. The reissue statute is a remedial provision that should be liberally construed. *In re Altenpohl*, 500 F.2d 1151, 1156 (C.C.P.A. 1974). Liberal construction is appropriate because the

⁸ Decisions of the CCPA are binding precedent on the Federal Circuit. *South Corp. v. United States*, 690 F.2d 1368, 1369-70 (Fed. Cir. 1982). At issue in *Henriksen* was whether a patent applicant could claim the benefit of one “similarly entitled” application, or more than one such application. 399 F.2d at 255.

statute is based on fundamental principles of equity and fairness. *In re Weiler*, 790 F.2d 1576, 1579 (Fed. Cir. 1986). The remedial provisions of the reissue statute should be liberally construed “in order to secure to inventors protection for what they have actually invented.” *In re Wadlinger*, 496 F.2d 1200, 1207-08 (C.C.P.A. 1974). “[T]he purpose of the reissue statute is to avoid forfeiture of substantive rights” *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1575 (Fed. Cir. 1991), *overruled on other grounds by Abbott Labs. v. Sandoz, Inc.*, ___ F.3d ___, 2009 WL 1371410 at *9 (Fed. Cir. May 18, 2009) (*en banc*).

In construing a statute, “we look not only to the particular statutory language, but to the design of the statute as a whole and to its object and policy.” *Crandon v. United States*, 494 U.S. 152, 158 (1990). After looking at the literal language of the statute, a court should look to the legislative history to further elucidate Congress’ intent. *In re Swanson*, 540 F.3d 1368, 1376 (Fed. Cir. 2008). Key portions of the reissue statute were adopted as parts of the Patent Acts of 1870 and 1928, and later recodified in the modern Patent Act of 1952.

(a) The Patent Act of 1870

In 1870, § 53 of the Patent Act added the language, as to the original patent, “the surrender of which shall take effect upon the issue of the amended patent,” and that “the commissioner may, in his discretion, cause several patents to be issued.” Patent Act of 1870, ch. 230, 16 Stat. 198, 198-217 (1870) (codified as amended at 35 U.S.C. §§ 251-52 (2006)) (Mulveny Decl. ¶ 13, Ex. L). The purpose of the 1870 amendment was to allow the patentee to enforce the original patent while a reissue application is pending.⁹ This purpose was announced by the Supreme Court following enactment of the Patent Act of 1870. *Allen v. Culp*, 166 U.S.

⁹ Representative Jenckes stated on the floor of the House that hearings were conducted, apparently between March 30 and April 14, 1870. See CONG. GLOBE, 41st Cong., 2nd Sess. 2297 (referring bill to committee), 2679-80 (Rep. Jenckes reporting back from committee) (1870) (Mulveny Decl. ¶ 14, Ex. M). However, searches at the Library of Congress and the Center for Legislative Archives were unsuccessful in finding the relevant committee records.

501, 504-05 (1897). Prior to 1870, an original patent was deemed surrendered upon the filing of an application for reissue. The Supreme Court explained that the prior practice led to an “injustice to inventors” in that “no rights could afterwards be asserted upon it, and that suits pending for an infringement of such patent fell with its surrender, because the foundation upon which they were begun no longer existed.” *Id.* at 504. Congress amended the statute in 1870 “[t]o obviate the injustice” by postponing the legal effect of surrender until such time that the reissue patent grants. *Id.* at 504-05. Thus, a clear purpose of delaying surrender is to permit an inventor to bring and maintain suits based on the original patent while the reissue application is pending before the Patent Office.

The words of the modern statute are substantially the same as those of the 1870 Act in this regard, “surrender of the original patent shall take effect upon the issue of the reissued patent.” 35 U.S.C. § 252. The purpose of delaying surrender under the modern statute until grant of “the reissued patent” is the same as it was under the 1870 Act: to allow patentees to enforce their original patents while reissue applications are pending. *See* 37 C.F.R. § 1.178(a) (“Until a reissue application is granted, the original patent shall remain in effect.”)

(b) The Patent Act of 1928

While the 1870 Patent Act corrected the “injustice to inventors” that an original patent could not be enforced while an application for reissue was pending (*Allen*, 166 U.S. at 504), another injustice remained. The second injustice was exemplified by the case of *Coffield v. Fletcher Mfg. Co.*, 167 F. 321 (6th Cir. 1909). In that case, the inventor filed for a reissue patent after suing an infringer. *Id.* at 321. The reissue patent was granted with the unchanged, single claim from the original patent and one additional claim. *Id.* at 321, 323. The trial court dismissed the action upon grant of the reissue and the Sixth Circuit affirmed. *Id.* at 323. The appellate court reasoned that the inventor had admitted the original patent to be defective upon

grant of the reissue and had surrendered same; and that under those circumstances, no cause of action for infringement prior to the reissue grant could be maintained. *Id.* at 322-23. Thus, while recognizing that surrender of the original patent did not occur until grant of the reissue patent, the Court dismissed the action for prior infringement upon reissue. *Id.*

In response to *Coffield* and cases like it, Congress passed the Patent Act of 1928. The Senate report from the Committee on Patents explained its purpose:

This bill . . . relating to reissues of patents is simply to correct an almost unbelievable and inequitable situation. Under the present law if a patentee applies for a reissue, no matter for what purpose, all rights he had in and under the original patent are forfeited ab initio upon the grant of the reissue.

S. Rep. No. 567, at 1, 70th Cong., 1st Sess. (1928) (Conf. Report) (Mulveny Decl. ¶ 15, Ex. N). Describing the state of the law exemplified by *Coffield* as “almost unbelievable and inequitable,” Congress amended the reissue statute in 1928 to ensure that claims for infringement of the original patent, which occurred while the reissue application was pending, could be maintained after grant of the reissue. S. Rep. No. 567, at 1 (1928). Specifically, the 1928 amendment added the language,

in so far as the claims of the original and reissued patents are identical, such surrender shall not affect any action then pending nor abate any cause of action then existing, and the reissued patent to the extent that its claims are identical with the original patent shall constitute a continuation thereof and have effect continuously from the date of the original patent.

Patent Act of 1928, ch. 730, 45 Stat. 732 (1928) (codified as amended at 35 U.S.C. §§ 251-52 (2006)) (Mulveny Decl. ¶ 16, Ex. O).

The intent of Congress and the objects and purpose of the reissue statute were clear when the Patent Act of 1928 was enacted: pre-existing infringements of a patent would not be abated by the grant of a reissue patent and surrender of the original. The patent rights exist continuously. The original patent remains in force until the exact moment when the reissue

patent comes into being. At that magic moment, the reissue patent reaches back to cover the subject matter of the original, capturing all prior infringements, and only then is the original patent surrendered.¹⁰

Thus, the 1928 statute mandated complete continuity between the original patent and its reissue, and ensures that actions brought under the original patent are not affected by the reissue. This mandate remains in the statute today, embodied in the language of 35 U.S.C. § 252, “such surrender shall not affect any action then pending nor abate any cause of action then existing,” and “the reissued patent, to the extent that its claims are substantially identical with the original patent, shall constitute a continuation thereof and have effect continuously from the date of the original patent.” *See also Hewlett-Packard*, 692 F. Supp. at 1131 (the statute “mandates surrender of the old only upon issuance of the new” when the original patent “has been completely replaced by the reissue.”) (emphasis added).

The purposes of the statutory provisions at issue: (1) to allow patentees to enforce their original patents while reissue applications are pending (*Allen*, 166 U.S. at 504-05); and (2) to ensure continuity of actions brought under the original patents (S. Rep. No. 567 at 1, (1928)), unambiguously demonstrate that surrender of an original patent occurs upon grant of the last reissue application. Were this not the case, and actions were to be dismissed upon grant of a first

¹⁰ At the time of the 1928 Patent Act, the provision of 35 U.S.C. § 251 on which the Board relied in *Graff* and on which Apotex now relies, had been part of the reissue statute for almost 100 years. The Patent Act of 1836 included the language, “it shall be lawful for the Commissioner, upon the surrender to him of such patent, and the payment of the further duty of fifteen dollars, to cause a new patent to be issued to the said inventor, for the same invention, for the residue of the period then unexpired for which the original patent was granted, in accordance with the patentee’s corrected description and specification.” Patent Act of 1836 (§ 13), ch. 357, 5 Stat. 117 (1836) (emphasis added) (Mulveny Decl. ¶ 17, Ex. P). Accordingly, Congress did not intend for this provision to interfere with the non-abatement and continuity provisions established in the 1928 Act.

reissue, the intent of Congress in enacting these provisions would be frustrated. Apotex's position is directly at odds with these provisions.

(3) Patent Office Rules Require Surrender of an Original Patent on Grant of the Last Reissue Application

Because the explicit language of the statute and the intent of Congress clearly require surrender of an original patent upon grant of the last reissue patent, the Court's analysis should end there. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43 (1984) ("If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.") The '995 patent is not yet surrendered, and will not be surrendered until all of the '995 reissue prosecution is concluded. However, even if the Court finds that the intent of Congress is unclear as to when an original patent expires when two reissue patents issue non-simultaneously, the result is the same. The Patent Office, in interpreting its own statute and regulations, has unequivocally clarified any ambiguity: "the surrender of a defective patent does not occur until all of the continuation or divisional reissue applications [from a first reissue application] are issued" *Okamoto*, 2006 WL 2523548, at *4.¹¹ Because the Patent Office's interpretation is based on a permissible construction of the statute, it should be upheld. *Chevron*, 467 U.S. at 842-43.

In order for an administrative decision to qualify for *Chevron* deference, a court must determine if the agency's interpretation of the statute was made pursuant to "a congressional

¹¹ Citation to unpublished decisions of the Board of Patent Appeals and Interferences as precedent is permissible. *Clevenger v. Martin*, 230 U.S.P.Q. 374, 375 n.2, 1986 WL 83592 ((Dec. Comm'r Pat. Feb. 11, 1986); see also B.P.A.I. Standard Operating Procedure 2 (Rev. 7) Publication Of Opinions And Binding Precedent, at 7 (Mar. 23, 2008) (Mulveny Decl. ¶ 18, Ex. Q.) (available at <http://www.uspto.gov/go/dcom/bpai/sop2.pdf>) ("Routine opinions that are cited by a party or that are publicly available may be cited for whatever persuasive value they may have"); *Ex Parte Holt*, 19 U.S.P.Q.2d 1211, 1991 WL 326550, at *3 (B.P.A.I. 1991) ("Of course, previously decided points of law must be followed unless overruled, and the application of the law to particular facts must be consistent from case to case.")

delegation of administrative authority.” *Tafas*, 559 F.3d at 1353 (quoting *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649 (1990)). “[T]he [Patent Office’s] interpretations of statutes that pertain to the [Patent Office’s] delegated authority are entitled to *Chevron* deference.” *Id.*

Administrative deference is not limited to notice-and-comment rulemaking procedures. An administrative agency “should be accorded *Chevron* deference when it gives ambiguous statutory terms meaning through a process of case-by-case adjudication.” *Immigration & Naturalization Serv. v. Aguirre-Aguirre*, 526 U.S. 415, 425 (1999). “[S]ubstantial deference is paid to an agency’s interpretations reflected in informal rulings.” *Am. Express Co. v. United States*, 262 F.3d 1376, 1382-83 (Fed. Cir. 2001). This rule applies to adjudicative decisions by the Patent Office, just as it does to other administrative agencies. *See Dickinson v. Zurko*, 527 U.S. 150, 165 (1999) (the standards of the Administrative Procedure Act apply to court review of PTO decisions); *see also Dethmers Mfg. Co. v. Automatic Equip. Mfg. Co.*, 272 F.3d 1365, 1379 (Fed. Cir. 2001) (Dyk, J., dissenting-in-part) (discussing *Zurko*, “we were clearly told that under the APA the PTO is to be treated like any other agency.”).¹² Indeed, the Federal Circuit has recognized that Patent Office decisions within the scope of its authority are entitled to deference. *Lacavera v. Dudas*, 441 F.3d 1380, 1382-83 (Fed. Cir. 2006).

**(a) Rules Relating to Timing of Reissue Grants and Surrender
Are Within the Authority Delegated to the Patent Office**

Congress delegated to the Patent Office authority to grant patents (35 U.S.C. § 2(a)(1)), and to establish regulations governing the conduct of proceedings (35 U.S.C. § 2(b)(2)(A)). The statute gives the Patent Office authority to make procedural rules. *Tafas*, 559 F.3d at 1353. In

¹² The majority of the three-member panel in *Dethmers Mfg.* applied a *de novo* standard of review for determining the necessary requirements of a reissue declaration. *Id.* at 1370. Neither party raised the issue of deference, and the majority opinion did not analyze the issue. *Id.* at 1370 n.2.

accordance with this authority, the Patent Office has established rules relating to the timing of reissue patent grants, the payment of reissue fees, and surrender of the original patents on which they were based.

Prior to 1997, the Patent Office maintained procedural regulations requiring that multiple reissue applications, based on the same original patent, be issued on the same day. 37 C.F.R. § 1.177 (1995) (Mulveny Decl. ¶ 19, Ex. R). Under the prior rules, if one reissue patent was deemed allowable, its issuance was held in abeyance until the remaining applications were also allowed.¹³ This procedure ensured that all reissues would grant simultaneously, and surrender of the original patent would occur at the time of the simultaneous grants.

Following the Federal Circuit's decision in *Graff*, the Patent Office changed its procedure to permit multiple reissue patents, including continuations from the same original patent, to issue at different times. 37 C.F.R. § 1.177 (2001) (Mulveny Decl. ¶ 21, Ex. T).¹⁴ In *Graff*, the Federal Circuit explained:

¹³ The prior rules relating to multiple reissues related to divisional patent applications, and did not address continuation reissue applications. The rules required that all divisional reissue patents be issued on the same day. "Unless otherwise ordered by the Commissioner upon petition . . . all the divisions of a reissue will issue simultaneously; if there is any controversy as to one division, the others will be withheld from issue until the controversy is ended, unless the Commissioner orders otherwise." 37 C.F.R. § 1.177 (1995); "It is important that divisional reissue applications be appropriately marked so that they 'will issue simultaneously' on the same day." MPEP 6th Ed., Rev. 1, § 1451 (1995) (Mulveny Decl. ¶ 20, Ex. S).

¹⁴ "Section 1.177 is amended to eliminate former requirements that divisional reissues be limited to separate and distinct parts of the thing patented, and that they be issued simultaneously unless ordered by the Commissioner. The rule is expanded to include continuations of reissues as well as divisionals." Changes To Implement the Patent Business Goals, 65 Fed. Reg. 54604, at 54644 (2000) (Mulveny Decl. ¶ 22, Ex. U). The Patent Office explained that "[f]ollowing *Graff*, the Office has adopted a policy of treating continuations/divisionals of reissue applications in much the same manner as continuations/divisionals of non-reissue applications. Accordingly, the former requirements of § 1.177 as to petitioning for non-simultaneous issuance of multiple reissue patents, suspending prosecution in an allowable reissue application while the other is

§ 251 does not bar multiple reissue patents in appropriate circumstances. Section 251[3] provides that the general rules for patent applications apply also to reissue applications, and § 251[2] expressly recognizes that there may be more than one reissue patent for distinct and separate parts of the thing patented. The statute does not prohibit divisional or continuation reissue applications, and does not place stricter limitations on such applications when they are presented by reissue, provided of course that the statutory requirements specific to reissue applications are met. *See* § 251[3].

. . . Section 251[2] is plainly intended as enabling, not as limiting. Section 251[2] has the effect of assuring that a different burden is not placed on divisional or continuation reissue applications, compared with divisions and continuations of original applications, by codifying the Supreme Court decision which recognized that more than one patent can result from a reissue proceeding. Thus § 251 [2] places no greater burden on Mr. Graff's continuation reissue application than upon a continuation of an original application; § 251[2] neither overrides, enlarges, nor limits the statement in § 251[3] that the provisions of Title 35 apply to reissues.

Id. at 876-77. *See* 65 Fed. Reg. 54604, at 54645 (2000) (Exhibit U) (explaining that revised § 1.177 eliminates, in accordance with *Graff*, a previous provision requiring applicants to specially petition for non-simultaneous issuance of continuation reissue applications.).

Under the new procedure, the Patent Office requires surrender of the original patent when the last reissue patent is issued. The Patent Office clarified this rule in *Okamoto*. 2006 WL 2523548, at *4. As stated earlier, the *Okamoto* examiner had rejected a continuation reissue application after a first reissue patent had been granted based on the theory that the original patent was surrendered upon grant of the first reissue, and thus a further reissue could not be granted. *Id.* The Board of Patent Appeals and Interferences overturned the Examiner, explaining that “the surrender of a defective patent does not occur until all of the continuation or divisional reissue applications are issued.” *Id.*

prosecuted, and limiting the content of each reissue application to separate and distinct parts of the thing patented, are all eliminated.” *Id.* at 54645 (Ex. U).

Apotex suggests that this Court should ignore the clear holding in *Okamoto* (alleging that it is dicta), and instead rely on 37 C.F.R. § 1.178(a). (Surrender Motion at 27-29.) Far from dicta, the interpretation set forth in *Okamoto* was the basis for overruling the Examiner in that case. 2006 WL 2523548, at *4-5. Particularly, the Examiner believed that the grant of the first reissue patent worked the surrender of the original patent, and thus that a second reissue patent could not be granted for want of the required act of concomitant surrender. *Id.* at *3. The Board's statement, "the surrender of a defective patent does not occur until all of the continuation or divisional reissue applications are issued" was directly related to its decision to overrule the Examiner. *Id.* at *4. Accordingly, the quoted language was an integral part of the holding, and the Board's decision in *Okamoto* is directly on point. Rule 1.178(a), on the other hand, merely paraphrases the language of the statute as to the timing of surrender: "surrender shall take effect upon reissue of the patent." 37 C.F.R. § 1.178. The purpose of the next sentence of Rule 1.178(a) is to clarify that the original patent remains enforceable during the reissue prosecution. It does so by referencing the time when "a reissue application is granted," again merely paraphrasing the statute. While not explicitly identifying which reissue application (when more than one is pending), Rule 1.178(a) must mean the last reissue application for the same reasons explained above in connection with the statute. *Okamoto*, which was unanimously decided by three Administrative Patent Judges fully aware of Rule 1.178, is the decisive rule on the issue at bar and should be accorded deference by this Court.

The Patent Office rules, allowing for the non-simultaneous grant of multiple reissue patents and incidental surrender of the original patent upon the last grant, are procedural in nature, and thus within the Patent Office's administrative authority. The Federal Circuit recently provided guidance on whether a rule is procedural in *Tafas*. 559 F.3d at 1351-1358. Whether or

not a rule affects individual rights and obligations is not determinative of the issue. *Id.* at 1354-55. In fact, most rules that are properly characterized as procedural affect individual rights and obligations. *Id.* at 1354-56. The Federal Circuit recognized “a spectrum [of rules] running from ‘procedural’ to ‘substantive’,” and noted that time schedules were “definitely at the procedural end.” *Id.* at 1356 (quoting *Lamoille Valley R.R. Co. v. Interstate Commerce Comm’n*, 711 F.2d 295, 328 (D.C. Cir. 1983)). The Federal Circuit concluded, among other things, that a rule limiting to two the number of continuation applications an inventor may file as a matter of right was procedural. *Id.* at 1349-50, 1354. In doing so, the court suggested that a procedural rule “could result in the loss of substantive rights” (citing *JEM Broad. Co. v. FCC*, 22 F.3d 320, 327-28 (D.C. Cir. 1994)), so long as “applicants will [not] be effectively foreclosed from obtaining the patent rights to which they are entitled.” *Tafas*, 559 F.3d at 1356.

Rules relating to timing are most often considered procedural in nature, even when substantive rights may be affected. For example, in *Ranger v. FCC*, a rule terminating the rights of would-be radio operators was considered procedural because it related to the timing of application submissions. 294 F.2d 240, 244 (D.C. Cir 1964). Likewise, in *Neighborhood TV Co. v. FCC*, a rule delaying the processing (and ultimate approval) of a challenger’s applications for broadcast licenses was deemed procedural because it did not preclude the grant of a license. 742 F.2d 629, 637-38 (D.C. Cir. 1984). The Patent Office rules at issue here are similar to those of *Ranger* and *Neighborhood TV*, in that they relate to timing, specifically when multiple reissue patents may be granted and when surrender occurs. 65 Fed. Reg. 54644 (Sept. 8, 2000) (“Section 1.177 is amended to eliminate former requirements that divisional reissues be...issued simultaneously.”); *Okamoto*, 2006 WL 2523548, at *4 (“the surrender of a defective patent does not occur until all of the continuation or divisional reissue applications are issued.”). The

underlying substantive right of an inventor to be granted multiple reissue patents and the attendant requirement that the original patent be surrendered have been part of the statute for over one hundred years (*Allen*, 166 U.S. at 504-05), and are not changed by the rules at issue.

Apotex alleges that the surrender of an original patent in a reissue setting is akin to expiration of the patent term, and thus substantive. (Surrender Motion at 24-25.) Apotex fails to appreciate the nature of the reissue process—a low risk, procedural mechanism to correct a defect in an issued patent. *Dresser*, 530 F. Supp. at 309-10. Expiration of the patent term, on the other hand, defines the length of time during which the patentee can enjoy exclusivity—the precise substantive right a patent confers. Particularly, the duration of the exclusive right is set by statute as a limited reward to the patentee for disclosing the invention and advancing technology. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989) (“The federal patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years.”) The exclusivity period is the substantive right conferred by patent. In sharp contrast, surrender of a patent during the reissue process and payment of the required fee does not effect the patent term (35 U.S.C. § 251 ¶ 1) or any other substantive right. Upon surrender, the original patent is simply replaced by its reissue. *Hewlett-Packard*, 692 F. Supp. at 1131 (The statute “mandates surrender of the old only upon issuance of the new” when the original patent “has been completely replaced by the reissue.”). No substantive rights are inherently changed in the process. The procedural act of surrender in connection with patent reissue and ultimate expiration are distinct and unrelated concepts.

The Patent Office rules simply affect the timing of when multiple reissue applications can be granted, and when surrender of the original patent occurs. Thus, these rules are procedural in

nature, and well within the Patent Office's delegated administrative authority. *Tafas*, 559 F.3d at 1354.

**(b) If the Court Finds the Statute Ambiguous, the Rule of
Okamoto is Entitled to *Chevron* Deference**

Because the rules at issue are within the scope of the Patent Office's delegated administrative authority, the Court should apply the two step analysis set forth in *Chevron*, 467 U.S. at 842-43. The first step is to determine whether Congress has directly spoken to the precise question at issue. *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1337-38 (Fed. Cir. 2008). For the reasons set forth above, the express language of the reissue statute and the intent of Congress in adopting it are clear: surrender of an original patent must occur at the time the last reissue patent is granted. See § V.B.(1), (2), *supra*. However, if the Court finds that the language of the statute and intent of Congress are ambiguous or uncertain as to the statute's meaning, then *Chevron* step one is satisfied and the Court should move on to step two. *Cooper Techs.*, 536 F.3d at 1337-38. According to *Chevron* step two, "if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Chevron*, 467 U.S. at 843. Thus, any ambiguity must be resolved in favor of the administrative agency's interpretation if that interpretation is "a permissible construction." *Cooper Techs.*, 536 F.3d at 1340-41.

For the reasons set forth above, the Patent Office's determinations as to when multiple reissue patents may be granted, and when surrender of the original patent occurs, are the most reasonable interpretations of the reissue statute. 35 U.S.C. §§ 251, 252; see § V.B.(1), (2), *supra*. For these same reasons, the Patent Office's interpretations are certainly "permissible constructions." The express language of the reissue statute mandates that: (1) "[t]he surrender of the original patent shall take effect upon the issue of the reissued patent,"; (2) to the extent that

the original and reissued patents are substantially identical, “such surrender shall not affect any action then pending nor abate any cause of action then existing, and the reissued patent...shall constitute a continuation thereof and have effect continuously from the date of the original patent,” (35 U.S.C. § 252 ¶ 1); and (3) “[t]he Director may issue several reissued patents.” (35 U.S.C. § 251 ¶ 2).

In order to uphold the purposes of the statute (*see* § V.B.(2), *supra*) and allow inventors to obtain multiple reissue patents at different times (*Graff*, 111 F.3d at 876-77), multiple reissue patents must be allowed to issue non-simultaneously, and the original patent must be enforceable while any one application in a family of multiple reissue applications remains pending. The Patent Office rules relating to these requirements, as set forth in 65 Fed. Reg. 54644 (Sept. 8, 2000) (“Section 1.177 is amended to eliminate former requirements that divisional reissues be...issued simultaneously”) and *Okamoto*, 2006 WL 2523548, at *4 (“the surrender of a defective patent does not occur until all of the continuation or divisional reissue applications are issued”), comply with the express requirements of the statute and achieve all of the goals in enacting it. Therefore, these rules are “permissible constructions.” *Cooper Techs.*, 536 F.3d at 1340-41.

Accordingly, this Court should give the Patent Office rules the deference to which they are entitled. *Chevron*, 467 U.S. at 843. Thus, the rules may only be overturned if inconsistent with a non-ambiguous provision of the statute. *Tafas*, 559 F.3d at 1359. Because the rules are not inconsistent with the statute, they should be upheld. *Id.*

(4) Surrender of the ‘995 Patent Will Occur Upon Conclusion of the ‘995 Reissue Proceedings

The reissue of the ‘995 patent presently involves two reissue applications: the original ‘830 reissue application and the second ‘897 continuation reissue application. *See* § IV.B.,

supra. The ‘830 reissue application recently issued as the RE667 patent. The ‘897 continuation reissue application is still pending before the Patent Office. Because an original patent is not surrendered until the last of multiple reissue patents is granted, the ‘995 patent remains in effect following the grant of the RE667 patent, and will subsist until the ‘897 continuation reissue application (or any further continuation applications) issues. 35 U.S.C. §§ 251-252; *Okamoto*, 2006 WL 2523548, at *4.¹⁵

The statute mandates that the original patent remains enforceable while a reissue application is pending (*Allen*, 166 U.S. at 504-05) and requires continuity between the enforceability of claimed subject matter in the original patent and its reissues (S. Rep. No. 567, at 1 (1928)). *See also* 35 U.S.C. § 252 (“[t]he surrender of the original patent shall take effect upon the issue of the reissued patent”, and to the extent that the original and reissued patents are substantially identical, “such surrender shall not affect any action then pending nor abate any cause of action then existing, and the reissued patent . . . shall constitute a continuation thereof and have effect continuously from the date of the original patent.”)

The requirements of interim enforceability, non-abatement, and continuity can only be achieved by permitting the ‘995 patent to subsist until the reissue proceedings have concluded, as explicitly set forth in the regulations, “[u]ntil a reissue application is granted, the original patent shall remain in effect.” 37 C.F.R. § 1.178(a). If this were not the case, the interim enforceability and continuity mandated by the statute would be achieved only with respect to the sole claim of

¹⁵ In the event that the ‘897 continuation reissue application ultimately fails to issue, the ‘995 patent would be surrendered at the time the ‘897 continuation reissue application or a continuation reissue application thereof is abandoned. Once an application is abandoned, no further applications can claim direct priority from it for want of the “copendency” requirement. *In re Doyle*, 293 F.3d 1355, 1363 (Fed. Cir. 2002).

the ‘995 patent carried forward into the RE667 patent (claim 6), and fail with respect to the substantially identical ‘995 claims still pending before the Patent Office.

Such a failure of continuity with respect to the subject matter of a still pending reissue application would mean that an inventor could assert only the subject matter covered by a first reissue while a later continuing reissue application is pending. In the present case, that would mean ignoring the existence of the pending ‘897 continuation reissue application and all of the same subject matter from the ‘995 patent claimed therein. Apotex asks this Court to do exactly that. Under Apotex’s proposal, the patentee would be deprived of all rights to assert the identical subject matter still pending before the Patent Office—the precise “injustice” that the amended statute was intended to avoid. *Allen*, 166 U.S. at 504. Apotex also asks this Court to return to the state of the law under *Coffield*, by ignoring the purpose of the Patent Act of 1928 and abrogating the goal of continuity of actions when a patent is replaced by its reissue—the very “unbelievable and inequitable” result the 1928 Act was meant to avoid. S. Rep. No. 567, at 1 (1928). Thus, the result urged by Apotex would frustrate the purpose of the statute, Supreme Court precedent, and the well-reasoned rule that surrender occurs upon grant of the last continuing reissue application. *Okamoto*, 2006 WL 2523548, at *4.

The cases upon which Apotex relies are inapposite. *Seattle Box Co. v. Indus. Crating & Packing, Inc.*, 731 F.2d 818, 827 (Fed Cir. 1984) and *Aspex Eyewear, Inc. v. E’Lite Optik, Inc.*, 2002 WL 31875577 (N.D. Tex. Dec. 20, 2002) both involved only one reissue application. The cases stand for the unremarkable proposition that when a lone reissue application is pending, the original patent is surrendered upon grant of that reissue. Thus, these cases are consistent with the rule that surrender occurs upon grant of the last (or only) continuing reissue application. Moreover, in *Aspex*, the case was dismissed upon surrender of the original patent only because

the plaintiff failed to properly seek leave to amend the complaint to include the newly reissued patent. 2002 WL 31875577, at *2. *Seattle Box* deals with the issue of whether a patentee can collect damages based on infringement of an original patent before it was surrendered upon reissue. 731 F.2d at 827. Neither case provides any insight as to when an original patent is surrendered when one reissue patent is granted but the reissue prosecution remains pending in the Patent Office.

The interpretation of 35 U.S.C. § 252 that provides the interim enforceability and continuity of actions demanded by the statute is that complete surrender of an original patent does not occur until all of its pending reissue applications have been granted. *Allen*, 166 U.S. at 504; S. Rep. No. 567, at 1 (1928); *Okamoto*, 2006 WL 2523548, at *4. Accordingly, the ‘995 patent remains in force until the ‘897 (or any further continuation) application issues.

(5) Survival of the ‘995 Patent Does Not Implicate Double Patenting

Apotex posits that there is a conflict between Pfizer’s construction of the reissue statute 35 U.S.C. §§ 251-252 and the prohibition against double patenting under 35 U.S.C. § 101. (Surrender Motion at 22.) Apotex does not cite a single case in which a court has even considered whether a claim in a reissue patent could be invalid for double patenting over claims in the original patent on which it was based; nor does it cite any legislative history demonstrating such a concern. The “balance being struck” by Congress between the reissue statute and § 101 is a figment of Apotex’s imagination.

The prohibition against double patenting prevents an inventor from obtaining two patents on the same subject matter or obvious variants thereof. *Takeda Pharm. Co. v. Doll*, 561 F.3d 1372, 1375 (Fed. Cir. 2009). Double patenting is found only when two coexisting claims of different patents cover the same subject matter. *General Foods Corp. v. Studiengesellschaft*

Kohle mbH, 972 F.2d 1272, 1282 (Fed. Cir. 1992) There is no double patenting issue in this case as alleged by Apotex because the subsisting claims of the ‘995 patent do not claim the same subject matter as the claims of the RE667 patent. Apotex fails to acknowledge that no two subsisting claims are the same in these patents, and reveals only in a footnote that its double patenting argument is premised entirely on a tortured hypothetical. (Surrender Motion at 19-20 note 13.) The problem with Apotex’s argument is apparent from Apotex’s own statement, “claim 6 of the ‘667 patent covers exactly the same subject matter that claim 6 of the ‘995 patent did.” (Surrender Motion at 19 (emphasis added).) Claim 6 of the ‘995 patent is not a valid claim because the Federal Circuit invalidated it in *Pfizer Inc. v. Ranbaxy*. 457 F.3d at 1291-92. Thus, Pfizer has only one existing claim to the subject matter of claim 6—that of the RE667 patent. Because no two subsisting claims cover the same subject matter, there is no double patenting.

Additionally, the invalidity of ‘995 claim 6 was the very reason reissue was required in the first place. Thus, there was no valid claim 6 in the ‘995 patent prior to the grant of the RE667 patent, and there is only one subsisting claim 6 after the grant of the RE667 patent. Apotex’s “what if” scenario¹⁶ confounds logic. Had claim 6 not been invalidated in *Ranbaxy*, Pfizer would have had no need to seek the reissue. In essence, Apotex asks this Court for an advisory opinion as to what the outcome would be if the facts were different—different in a way that would have negated the need for reissue to begin with.

Even assuming, *arguendo*, that Apotex’s hypothetical scenario raises a ripe issue (which it does not), there can be no double patenting as between a reissue patent and the original patent for a very simple reason: the former is by definition a reissued form of the latter. They are, in effect, one and the same. The point can be exemplified by considering the purpose of the

¹⁶ Apotex alleges that double patenting would exist if Pfizer had sought reissue of claim 6 before it had been invalidated.

prohibition against double patenting, which is to prevent unlawful extensions of the patent term by obtaining multiple, sequential patents on the same subject matter. *In re Kaplan*, 789 F.2d 1574, 1579-80 (Fed. Cir. 1986) (“All proper double patenting rejections, of either [same invention or obviousness] type, rest on the fact that a patent has been issued and later issuance of a second patent will continue protection, beyond the date of expiration of the first patent”) (emphasis altered); *Odiorne v. Amesbury Nail Factory*, 18 F. Cas. 578 (C.C.D. Mass. 1819) (Case No. 10,430) (“if [the patentee] can successively take out at different times new patents for the same invention, he may perpetuate his exclusive right during a century, whereas the patent act confines this right to fourteen years from the date of the first patent.”); *see also Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 198 (1894) (citing *Odiorne*); MPEP § 804 (Mulveny Decl. ¶ 24, Ex. V).

When a patent is reissued, such as the ‘995 patent, the newly granted reissue patent does not have a new term. It has the effective filing date of the patent on which it is based and takes on the unexpired portion of the original patent term. 35 U.S.C. § 251 ¶ 1. A reissue patent is not a new patent of the type with which double patenting is concerned. Rather, the reissue is an amended version of the original patent. *See* 35 U.S.C. § 252 (“the reissued patent, to the extent that its claims are substantially identical with the original patent, shall constitute a continuation thereof”); *Hewlett-Packard*, 692 F. Supp. at 1131 (discussing the continuity between original and reissue patents, and characterizing the reissue as an “amended edition” of the original). MPEP 8th Ed., Rev. 7, § 1460 (2008) (Ex. C) (“With respect to the Office treatment of the reissued patent, the reissued patent will be viewed as if the original patent had been originally granted in the amended form provided by the reissue.”).

Because a reissue patent is an “amended edition” of the original patent, and not a new patent with a new (or otherwise extended) term, it cannot be the basis of a double patenting problem. For this reason, no court has ever found a reissue patent invalid for double patenting over the original patent on which it was based, or *vice versa*, as far as Pfizer is aware. Not surprisingly, Apotex has not cited any such case. Accordingly, the grant of the RE667 patent and continued subsistence of the ‘995 patent does not and cannot constitute double patenting.

C. Alternatively, if Surrender is a Concomitant Requirement of the Grant of a First of Multiple Reissue Patents, It Must Be Only Partial Surrender

An alternative reading of the statute prohibits complete surrender of the original patent upon grant of the first of multiple reissue patents. If the Court construes § 251 as requiring a concomitant act of surrender as a strict requirement for the grant of a reissue patent (as Apotex suggests), then the statute should be interpreted to effect only a partial surrender of the original patent at the time of the first reissue grant—the scope of the surrender being limited to the claims of the original patent that issued in the first reissue patent.

More particularly, if an act of surrender is strictly required at the moment a reissue patent is issued, then the initial surrender (at the time the first reissue is granted) must be a partial surrender to ensure that part of the original patent is available to be surrendered later (when one or more subsequent reissue patents are granted). If a full surrender occurred at the time of the first reissue grant, there would be nothing left to surrender at the time the later reissue patent were issued and, indeed, there would be nothing left to reissue because the original patent had been surrendered. Thus, it would be impossible to obtain two or more reissue patents at different times on the same original patent as explicitly authorized by *Graff*. 111 F.3d at 876-77.

As noted above, the Board in *Ex Parte Graff* held that the original patent had been surrendered upon issue of the first reissue patent, and that no later reissue patent could be granted

because the original patent was no longer available to surrender. 1996 WL 33693209, at *5-*6. The Board relied on the very same provision of 35 U.S.C. § 251 on which Apotex now relies, “the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent”, and also like Apotex, reasoned that it established a concomitant act of surrender as a strict requirement for the grant of the first reissue patent. *Id.* at *6. The Board rejected the applicant’s second reissue application, stating “Nor could the [original] patent be surrendered upon issuance of the present second reissue application as required by the first paragraph of 35 U.S.C. § 251 since the [original] patent was already surrendered.” *Id.*

The Federal Circuit reversed the Board on all grounds relating to the allegedly “surrendered [original] patent”.¹⁷ *Graff*, 111 F.3d at 876-877. To the extent that this Court interprets 35 U.S.C. § 251 to require some act of surrender at the time a first (of two or more) reissue patent is granted, it must at most be only a partial surrender, *i.e.*, it must be surrender of only the portion of the original patent embodied in the claims of the first reissue. All claims in the original patent not corresponding to claims in the first reissue patent must be outside the scope of the initial, partial surrender so that those claims are available for surrender upon grant of the later reissue application in which their corresponding claims are pending.

An interpretation of *Graff* that supports the alternative reading of 35 U.S.C. §§ 251-252 (prohibiting only complete surrender of the original patent, but permitting partial surrender, upon grant of the first of multiple reissue patents), would uphold the purposes of the statute by maintaining causes of action between the grant dates of the first and later reissue patents.

¹⁷ As explained in Section V.B.(1)(b), *supra*, the Federal Circuit’s decision in *Graff* indicates that surrender of an original patent does not occur until the last of multiple reissue applications is granted.

Moreover, the interpretation would impart consistency to the reissue process by providing some form of surrender when both the first and later reissue grants occur. As Apotex would have it, a complete surrender of the original patent would occur at the time the first reissue was granted and nothing would be left to surrender at the time of the later reissue grant. Apotex's own urging that surrender must occur concomitantly with the grant of a reissue patent shows that a complete initial surrender at the time of the first reissue grant is unworkable as to the later reissue patent. *See* 35 U.S.C. § 251 ("the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent.")

Moreover, Apotex's interpretation of § 251 may lend credence to the alternative partial surrender interpretation. As Apotex would have it, the quoted statutory provision would require a concomitant act of surrender and fee payment each time a reissue patent is granted. When multiple reissue patents issue from a single original patent, the statute (under Apotex's interpretation) would require multiple acts of surrender and multiple issue fee payments. This could be accomplished only through initial, partial surrender.

Even under the alternative reading of partial surrender, claims of the original patent not corresponding to claims in the first reissue patent must remain pending and available for surrender until the reissue prosecution is complete. Accordingly, the claims of the '995 patent presently pending in the '897 continuation reissue application (*i.e.*, claims 1-5 and 7-12) are not surrendered.

D. Dismissal Under Fed. R. Civ. P. 12(b)(1) or (6) Is Not Justified

The cases cited by Apotex in support of dismissal are wholly inapplicable to the facts of this case. *Belk, Inc. v. Meyer Corp.*, 2008 WL 2704792 (W.D.N.C. July 7, 2008), for example, relies on a different statute altogether: 35 U.S.C. § 253, which governs statutory disclaimers. *Id.* at *3. There, the plaintiff sought declaratory judgment of non-infringement on a patent that the

defendant patentee had voluntarily disclaimed. *Id.* Following such a disclaimer, there can be no case or controversy regarding infringement. *Id.* at *4. This proposition is irrelevant to the case at bar.¹⁸

Surrender of a patent in favor of a reissue patent is not the equivalent of a voluntary disclaimer, in part due to the continuity of actions mandated by 35 U.S.C. § 252. Setting that aside, however, there has been no surrender of the ‘995 patent. *See* Section V.B., *supra*. Pfizer has certainly not voluntarily disclaimed the ‘995 patent nor performed any act that could be construed as a disclaimer. The ‘995 patent is still in force and remains asserted against Apotex for its ANDA filing. Therefore, the infringement claims based on the ‘995 patent should not be dismissed under Fed. R. Civ. P. 12(b)(1).

For many of the same reasons, Pfizer has sufficiently pleaded a case in both its original and Amended Complaint to survive a 12(b)(6) challenge. In this respect, Apotex’s reliance on *Aspex* is misplaced. As noted above, *Aspex* involved a case in which an original patent had unquestionably been surrendered in favor of a reissue patent, and the patentee failed to properly seek leave to amend the complaint to add the reissue. 2002 WL 31875577, at *2. Instead, the patentee had filed a new action based on the reissued patent. *Id.* Under that circumstance, no patent existed in the original case, which was thus dismissed for failure to state a claim. *Id.*

In sharp contrast, the present case involves well pleaded counts of infringement under 35 U.S.C. § 271(e)(2) with respect to the still-pending ‘995 patent (as well as the RE667 patent).

¹⁸ The other cases cited by Apotex in support of dismissal are equally inapplicable: *Cytologix Corp. v. Ventana Med. Sys., Inc.*, 2007 WL 3037404 (D. Mass. Oct. 17, 2007) (no case or controversy where plaintiff no longer owned the asserted patents); *Black & Decker Inc. v. Robert Bosch Tool Corp.*, 371 F. Supp. 2d 965 (N.D. Ill. 2005) (no case or controversy with respect to unasserted patent claims); *W.L. Gore & Assoc. v. Oak Materials Group, Inc.*, 424 F. Supp. 700 (D. Del. 1976) (disclaimer of patent claims). In the present case, Pfizer still owns the ‘995 patent (and the RE667 patent); the patents have not been disclaimed; and the patents remain asserted.

(D.I. 25 ¶¶ 46-56.) Given that the ‘995 patent is in force, the counts set forth in each of the Complaint and Amended Complaint are sufficient to survive a challenge under Fed. R. Civ. P. 12(b)(6). “[A] patentee need only plead facts sufficient to place the alleged infringer on notice as to what he must defend.” *McZeal v. Sprint Nextel Corp.*, 501 F.3d 1354, 1357 (Fed. Cir. 2007). Because the ‘995 patent is in force and has been adequately pleaded, the ‘995 infringement claims should also not be dismissed under Fed. R. Civ. P. 12(b)(6).

VI. Conclusion

For the reasons set forth above, Pfizer respectfully submits that the original Complaint and Amended Complaint each state appropriate causes of action under 35 U.S.C. § 271(e)(2) against Apotex for infringement of the ‘995 patent. Thus, Pfizer requests that Apotex’s motion be denied.

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Dated: May 26, 2009

CERTIFICATE OF SERVICE

I hereby certify that on May 26, 2009, a true copy of the foregoing *Plaintiffs' Brief In Opposition to Defendants Apotex Inc. and Apotex Corp.'s Fed. R. Civ. P. Rule 12(b)(1) and (6) Motion To Dismiss All Claims of Infringement Based on the '995 Patent* was electronically filed with the Clerk of the Court using CM/ECF which will send notification of such filing to the following and the document is available for viewing and downloading from CM/ECF:

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I hereby certify that on May 26, 2009, I have sent by U.S. Mail the foregoing document to the following non-registered participant:

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